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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,351	04/21/2004	Manja Ahola	TUR-140-A	6705

32954 7590 11/30/2005

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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/828,351	Applicant(s) AHOLA ET AL	
	Examiner Susan T. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-31 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23-28 and 31 is/are rejected.
- 7) ☐ Claim(s) 29 and 30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/29/05;04/21/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of applicant Preliminary Amendment filed 04/29/05, and Information Disclosure Statement filed 04/29/05 and 04/21/04.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23 and 26-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 5-12 of U.S. Patent No. 6,764,690 ('690). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '690 patent claims a method of administering a biologically active agent or agents to a human or animal comprising implanting, injecting or mucosally attaching a delivery device for the controlled release of a biologically active agent or agents comprises a dissolvable silica-xerogel produced by a sol-gel process (see claims 12 and 1). Biologically active agent or agents are found in claims 5-8. The '690 patent does not explicitly recites the silica-xerogel is

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capable of dissolving totally during a desired period when in contact with body fluids.

However, it is the position of the examiner that such limitation is clearly inherent

because the '690 patent uses the same silica-xerogel made by the same materials and

process. When the claimed and prior art products are identical or substantially identical

in structure or composition, or are produced by identical or substantially identical

processes, a prima facie case of either anticipation or obviousness has been

established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Products of identical chemical composition cannot have mutually exclusive properties.

A chemical composition and its properties are inseparable. Therefore, if the prior art

teaches the identical chemical structure, the properties applicant discloses and/or

claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655,

1658 (Fed. Cir. 1990). Accordingly, the instant claims are anticipated by the claims of

the '690 patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ducheyne et al. US 5,591,453, in view of Einarsrud et al. US WO 92/20623.

Ducheyne teaches a controlled release matrix carrier comprising silica based glass prepared by a sol-gel process (see abstract; and column 8, lines 43-67). The silica based glass further comprising calcium (column 10, lines 8-10). Ducheyne further teaches biologically active molecules are incorporated within the matrix (see abstract). Biologically active molecules include drugs, growth factors, cytokines, antibiotics, anti-inflammatory agent, and analgesics (column 9, lines 54-64). Ducheyne also teaches the matrix is suitable for administration as an implant in the form of granules, discs, or monoliths (column 10, lines 8-16).

Ducheyne does not teach the silica-xerogel. However, silica-xerogel is well known as a silica based glass compound in pharmaceutical art. To be more specific, Einarsrud teaches silica-xerogel has high porosity and therefore suitable to be used as a composite material and carrier for catalyst and liquids (page 1, lines 25-27). Thus, it would have been obvious to one of ordinary skill in the art to modify the teaching of Ducheyne using the silica-xerogel as a silica based glass to obtain the claimed invention, because Ducheyne teaches the use of silica based glass in a composite composition (column 6, lines 32-34), because Ducheyne teaches the desire to use porous material (column 10, lines 8-21), because Ducheyne teaches using a sol-gel

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process to obtain a microporosity sol-gel glass that can control the release of the biologically active molecules (column 9, lines 5-19), because Ducheyne teaches silica-based includes silicon oxide, and other oxides (column 9, lines 50-52), and because Einarsrud teaches using high porosity material such as silica xerogel as a composite material.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mayer et al., Ryu, Zhong et al., Liu et al., Babich et al., and Straub et al. are of interest for teachings of porous matrix comprising silica gel materials.

Claims Allowable

Claims 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Tran
Patent Examiner
Art Unit 1615



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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